



DEPARTMENT OF HEALTH AND HUMAN SERVICES

91521d  
Food and Drug Administration  
Cincinnati District Office  
6751 Steger Drive  
Cincinnati, OH 45237-3097  
Telephone: (513) 679-2700  
FAX: (513) 679-2772

**WARNING LETTER**

Cin WL -9558-01  
August 10, 2001

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

William Daniel II, M.D.  
Chief of Staff  
Baptist Regional Medical Center  
Radiology Department  
1 Trillium Way  
Corbin, KY 40701

Facility I.D.#: 152918

Dear Dr. Daniel:

A representative from the Commonwealth of Kentucky acting on behalf of the Food and Drug Administration (FDA) inspected your facility on July 31, 2001. This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act (MQSA) of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 finding at your facility:

**Quality Assurance – Equipment – *Weekly Quality Control Tests* -21 CFR 900.12(e)(2)**

Your records revealed that your facility phantom quality control records for the two mammography units were missing for four (4) weeks. The MQSA regulation requires each mammography unit be evaluated by performing at least weekly the image quality evaluation test. The inspection found that your facility failed to perform this quality control test during the weeks of April 30-May 4, May 29-June 1, June 11-15 and June 25-29, 2001.

Because this condition may be symptomatic of serious underlying problem that could compromise the quality of mammography at your facility, this represents violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against performing further mammography.

You must act on this matter immediately. Please explain the following elements to this office in writing within fifteen (15) working days from the date you received this letter:

- The specific steps you have taken to correct the violation noted in this letter; and
- Each step your facility is taking **to prevent the recurrence of similar violation.**

Please submit sample records that demonstrate proper record keeping procedures, if the finding relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to:

Mr. R. Terry Bolen  
MQSA Compliance Officer  
Food & Drug Administration  
6751 Steger Drive  
Cincinnati, OH 45237-3097  
FAX: 513-679-2772

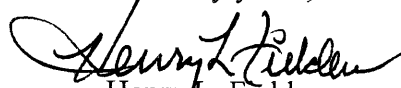
Also, please send a copy to the State radiation control office:

Mr. James Barnes  
Commonwealth of Kentucky  
Radiation Control  
275 East Main St.  
Frankfort, KY 40621

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at <http://www.fda.gov/cdrh/mammography>.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Mr. R. Terry Bolen at 513-679-2700, extension 138

Sincerely yours,



Henry L. Fielden  
District Director  
Cincinnati District Office

c.  
KY/JBarnes

Priscilla F. Butler, M.S.  
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American College of Radiology  
1891 Preston White Dr.  
Reston, VA 20191